DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Kent Hinkson
Healthy-Living.org
1098 South 890 East
Orem, UT 84097

Dear Mr. Hinkson:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.healthy-living.org and has determined that the product RiSoTriene is promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site include:

RiSotriene

- "Beneficial for Some Diabetics: Jim Fly, an insulin dependent diabetic for 26 years, after trying every kind of vitamin supplement with scant improvement, went from 120 units of insulin a day to zero, in just two years of eating RiSotriene."

- "Has Helped People with Multiple Sclerosis: Joanne Frazel's mother died of MS, after years of failed, miserable, expensive medical treatment. So when Joanne was diagnosed she took a different route and completely overcame Multiple Sclerosis in just two years. Her regimen included eating RiSotriene daily. When she began eating RiSotriene she was 100% blind in one eye and 80% blind in the other and couldn't walk across a room unassisted. She began eating RiSotriene five years ago. During a period of two years during which she ate RiSotriene several times per day, her eyesight returned, her balance and other MS symptoms disappeared. Continuing to eat RiSoTriene through the current time, she has absolutely no MS symptomology."

- (under the heading "Has Helped People Lower Cholesterol): "Eddie LeBaron ate RiSotriene faithfully from is first blood check on December 7, 2002 until his next one on April 1 (4 months later). Here are the results: Total cholesterol dropped from 207 to 154 and TC/HDL ratio dropped from 249 to 133."

- "Dr. Mark Drucker, M.D. and Director for the Advanced Center for Medicine in Encinitas, California, states, "With the help of RiSotriene, we have also been able to stabilize our diabetic patients. After only two weeks, most are able to reduce their dosages of insulin or oral diabetic medication by 50 percent. In four to eight weeks, many Type II diabetics are able to reduce or discontinue their oral medication."

- "RiSoTriene is considered by some to be a potent tool against disease. Some of the diseases that people have found to respond to this nutritional breakthrough include: diabetes, arterial plaque and cholesterol, multiple sclerosis, cancer, heart disease, lupus, ulcers and much more."

Your web site also contains disease claims in the form of testimonials, including:

- "My diabetes has been raging out of control for the last three years. … No matter how many remedies I tried over the last three years - everything from taking vitamins to doing martial arts - I still found that my blood sugar level was too high. Right after I started taking RiSoTriene, I noticed major change in my blood sugar level. Every day I record my blood sugar reading in a little book, and all of my readings before taking this product were in the 200s to 400s, which is very high. The day after I took RiSoTriene for the first time, my blood sugar reading was 164! … Now I've even been able to reduce the amount of insulin I take. "

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. Your product RiSoTriene is also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for this drug fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. While reviewing your web site, we noticed that you promote other products for disease treatment and/or prevention. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your web site, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you

respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be addressed to Kristen Moe, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you prefer to respond electronically, send your e-mail to kristen.moe1@FDA.HHS.GOV. If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition